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| 10/711,886 | 10/12/2004 | Yandong Jiang | 022727-0117 | 5885 |
| 21125 7590 04/04/2007 NUTTER MCCLENNEN & FISH LLP WORLD TRADE CENTER WEST 155 SEAPORT BOULEVARD BOSTON, MA 02210-2604 | | | EXAMINER JACKSON, BRANDON LEE | |
| | | | ART UNIT 3772 | PAPER NUMBER |
| SHORTENED STATUTORY PERIOD OF RESPONSE | | MAIL DATE | DELIVERY MODE | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/711,886

Applicant(s)

JIANG, YANDONG

Examiner

Brandon Jackson

Art Unit

3772

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 March 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-29 is/are pending in the application.
- 4a) Of the above claim(s), _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 October 2004 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION

This action is in response to arguments submitted on 03/17/2007. Currently claims 1 and 3-29 are pending in the application.

Response to Arguments

Applicant's arguments with respect to claim 1 and 3-29 have been considered but are moot in view of the new ground(s) of rejection.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 3-5 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3 of

compending Application No. 11021157 (US 2005/0166929) in view of Tuck (US 6,923,181).

The limitations of claim 1 of the instant invention can be found in claim 1 of Application No. '157 except for the limitation of a nasal mask as part of the device. However, Tuck teaches a nasal mask (Figure 2) adapted to deliver gases through the patient's nasal passageway [0034]. Since this is a nasal mask, the delivery of gas taught by Tuck is through the nasal passageway.

Therefore, it would have been obvious, to one having ordinary skill in the art at the time of the invention, to modify claim 1 of the instant application so that it would include the nasal mask taught by Tuck, as making this modification would result in a patient being able to obtain an artificial gas supply.

The limitations of claim 3 of the instant invention can be found in claim 1 of Application No. '157 except for the limitation of "prevent the patient's soft tissues of the upper airway from collapsing." However the mouthpiece is capable to be adapted to perform this function.

The limitations of claim 4 of the instant invention can be found in claim 2 of Application No. '157. Although the conflicting claims are not identical, they are not patentably distinct from each other because their difference lies only in the fact that the claim language terminology are synonymous with one another between the two conflicting applications.

The limitations of claim 5 of the instant invention can be found in claim 1 of

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Application No. '157. The difference between claim 5 of the instant invention and claim 1 of the application lies in the fact that the application claim positively recites connection of the tube to a negative pressure generator while application '157, claim 1, recites that that tube is "adapted to be connected to negative pressure generator. Therefore, it is obvious that the device of each claim can be connected to a negative pressure generator, and so they are not patentably distinct from one another.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 3-8, 10-15, and 17-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kulick (U.S. 6,494,209) in view of Cannon (U.S. 7,021,312) and Blachy et al. (U.S. 4,270,531) and Curti (US 6,665,385). Kulick discloses mouthpiece 1 adapted to be coupled to a negative pressure generator 8 that is effective to create a

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negative pressure within the oral cavity to prevent the patient's soft tissues of the upper airway from collapsing (column 2, lines 41-44). Low suction pressure is equivalent to negative pressure. Kulick further discloses that "it is one object of the present invention to provide a method and apparatus for reducing or eliminating snoring, hypopnea, or apnea by holding the tongue in a forward position in such a way that no portion of the tongue or other oral soft tissue will vibrate during breathing" (column 2, lines 46-50). This is equivalent to saying that an object of Kulick's invention is to prevent soft tissues of the upper airway from collapsing.

Kulick does not expressly disclose a nasal mask adapted to deliver gases through the patient's nasal passageway or that the mouthpiece will seal the patient's mouth.

However, Cannon teaches a nasal mask (14) connected to a mouthpiece (12) (See Figure 1) adapted to deliver gases through the patient's nasal passageway (column 2, lines 34-40). Therefore, it is obvious to one skilled in the art to use a nasal mask in combination with a mouthpiece in order to deliver CPAP treatment and remedy sleep apnea and similar disorders (column 3, lines 45-50). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the invention of Kulick to incorporate a nasal mask for delivery of gases through the patient's nasal passageway as such is well known in the art as taught by Cannon.

Blachy teaches a mouthpiece (fig. 2) adapted to seal (col. 2, lines 42-48) the mouth of the user and also adapted to be coupled with a nasal occluder (col. 3, lines 42-45). The mouthpiece (fig. 2) is interchangeable with that of Kulick because it has

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connection means for (22) a ventilator (14), and a bite block (12). The two devices are structurally equivalent. Therefore it would be obvious to one of ordinary skill in the art to modify the mouthpiece (1) of Kulick with the front surface (46) and gum-engaging surface (34), as taught by Blachy, because the front surface prevent atmospheric air from penetrating and affecting the airflow.

With respect to claim 3, Kulick in view of Cannon and Blachy teaches that the mouthpiece (1, Kulick) is effective to prevent the patient's soft tissues of the upper airway from collapsing without impinging on the tongue (column 2, lines 46-50, Kulick).

With respect to claim 4, Kulick in view of Cannon teach that the mouthpiece (1, Kulick) includes upper and lower portions that conform to an anatomy of the patient's upper and lower dental structures. Kulick discloses bite blocks (2) located near the first molar teeth to limit the closure of the teeth (See Brief Description of the Drawing Figures, Figure 7's Description). Kulick's bite blocks (2) contain upper and lower portions that serve to conform to an anatomy of the patient's upper and lower dental structures.

With respect to claim 5, Kulick discloses wherein the mouthpiece 1 includes a hollow elongate member (7) extending therefrom and coupled to a negative pressure generator (See Figure 2 and column 4, lines 10-11, Kulick).

With respect to claim 6, Kulick in view of Cannon and Blachy teaches a nasal mask (38) coupled to a mouthpiece. Therefore it would be obvious to one of ordinary skill in the art to modify the mouthpiece of Kulick to be coupled to the mask (38) of as it is well known in the art to stabilize a nasal mask to a user's face by means of a

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mouthpiece as taught by Cannon. In addition, Goldstein (US 6,012,455) teaches that the combination of a nasal mask and a mouthpiece is used to reliably provide breathable air to the nasal passages, even during sleep (column 1, lines 60-65).

With respect to claim 7, Kulick in view of Cannon and Blachy discloses a conventional source of suction (8, Kulick), which is the same as a negative pressure generator. The difference between Kulick and claim 7 is that Kulick does not disclose a nasal mask coupled to a device selected from the group consisting of a continuous positive airway pressure device, a mechanical ventilation device, and a positive end expiratory pressure device. Cannon, however, teaches a nasal mask 14 using CPAP treatment (column 3, lines 45-48). It is therefore well known in the art to use a nasal mask coupled to a device, such as a CPAP device to maintain sufficient pressure in an upper airway of a patient to prevent collapse of the patient's soft tissues.

Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the invention of Kulick to include the nasal mask coupled to a CPAP device of Cannon in order to maintain sufficient pressure in an upper airway of a patient to prevent collapse.

With respect to claim 8, as stated above in claims 1 and 6, the difference between Kulick and claim 8 is that Kulick does not disclose a nasal mask coupled to a device selected from the group consisting of a continuous positive airway pressure device, a mechanical ventilation device, and a positive end expiratory pressure device. Cannon teaches a nasal mask 14 using CPAP treatment (column 3, lines 45-48). It is therefore well known in the art to use a nasal mask coupled to a device, such

as a CPAP device, or other selected device, to maintain sufficient pressure in an upper airway of a patient to prevent collapse of the patient's soft tissues.

Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the invention of Kulick to include the nasal mask coupled to a CPAP device of Cannon in order to maintain sufficient pressure in an upper airway of a patient to prevent collapse.

With respect to claim 10, Kulick discloses mouthpiece 1 adapted to substantially seal an oral cavity within a patient's mouth and adapted to be coupled to a negative pressure generator 8 that is effective to create a negative pressure within the oral cavity to prevent the patient's soft tissues of the upper airway from collapsing (column 2, lines 41-44). Kulick further discloses that "it is one object of the present invention to provide a method and apparatus for reducing or eliminating snoring, hypopnea, or apnea by holding the tongue in a forward position in such a way that no portion of the tongue or other oral soft tissue will vibrate during breathing" (column 2, lines 46-50). This is equivalent to saying that an object of Kulick's invention is to prevent soft tissues of the upper airway from collapsing.

Kulick does not expressly disclose a tubular member adapted to deliver gases through the patient's nasal passageway.

However, Cannon teaches a nasal mask (14) connected to a mouthpiece (12) (See Figure 1) adapted to deliver gases through the patient's nasal passageway (column 2, lines 34-40) demonstrating that it is well known in the art to use a nasal mask in combination with a mouthpiece in order to deliver CPAP treatment and remedy

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sleep apnea and similar disorders (column 3, lines 45-50). Cannon teaches a nasal mask 14.

Cannon does not teach the nasal mask 14 having first and second tubular members extending therethrough and in communication with the patient's nasal passageway, with the first tubular member being adapted to deliver gases through the patient's nasal passageway and the second tubular member being adapted to allow a gas sample to be taken from the nasal passageway.

However Curti in a nasal cannula teaches first 13 and second 14 tubular members being adapted to deliver gases through the patient's nasal passageway with the first tubular member being adapted to deliver gases through the patient's nasal passageway and the second tubular member 14 being adapted to allow a gas sample to be taken from the nasal passageway. "The preferred nasal cannula used in this procedure is a cannula which insufflates the patient with oxygen through one nare of a cannula and separately samples the exhaled gases by drawing the exhaled gas from the other nare into a conventional carbon dioxide analyzer" (Background of the Invention, Column 1, Lines 15-20). It would be obvious to modify the face mask of Bibi to include the nasal cannula of Curti, as doing so would allow one to supply oxygen through one tubular member and allow a gas sample to be taken from the other tubular member.

It would have been obvious to one of ordinary skill in the art to use the teachings of Cannon in combination with Curti to modify the face mask of Kulick to include first and second tubular members so that a patient could be provided with oxygen through

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one nasal passageway and so that a gas sample of carbon dioxide could be obtained from the patient's other nasal passageway.

With respect to claim 11, Kulick in view of Cannon and Blachy teaches a nasal mask 38 coupled to a mouthpiece. Cannon does not teach tubular members but rather teaches a nasal mask. It would have been obvious to substitute nasal mask of Cannon with the tubular members of Curti, as the modification would result a patient being provided with oxygen through one nasal passageway and the allowing a gas sample of carbon dioxide to be obtained from the patient's other nasal passageway.

With respect to claim 12, Kulick in view of Cannon and Blachy, and further in view of Curti teach wherein the mouthpiece 1 is effective to prevent the patient's soft tissues of the upper airway from collapsing without impinging on the tongue. "It is one object of the present invention to provide a method and apparatus for reducing or eliminating snoring, hypopnea, or apnea by holding the tongue in a forward position in such a way that no portion of the tongue or other oral soft tissue will vibrate during breathing" (column 2, lines 46-50).

With respect to claim 13, Kulick in view of Cannon and Blachy, and further in view of Curti teach a conventional source of suction 8, which is the same as a negative pressure generator.

With respect to claim 14, Kulick in view of Cannon and Blachy, and further in view of Curti teach wherein tubular members 50 comprise a nasal mask 14 that is adapted to form a seal with the nasal airway (Figure 1 - Cannon).

With respect to claim 15, Kulick in view of Cannon and Blachy, and further in view of Curti teach that nasal mask 38 is coupled to a continuous positive airway device (column 3, lines 45-50 - Kulick).

With respect to claim 17, Kulick discloses a mouthpiece 1 forming a substantially sealed oral cavity within a patient's mouth, creating a negative pressure within the substantially sealed oral cavity effective to prevent the patient's soft tissues of the upper airway from collapsing by means of a negative pressure generator 8 (Kulick).

Kulick does not expressly disclose delivering gases through the patient's nasal passageway.

However, Cannon teaches a nasal mask (14) connected to a mouthpiece (12) (See Figure 1) adapted to deliver gases through the patient's nasal passageway (column 2, lines 34-40) so it is therefore well known in the art to use a nasal mask in combination in order to deliver CPAP treatment and remedy sleep apnea and similar disorders (column 3, lines 45-50).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the invention of Kulick to incorporate a nasal mask for delivery of gases through the patient's nasal passageway as such is well known in the art as taught by Cannon.

The method steps of forming a substantially sealing oral cavity within a patient's mouth, creating a negative pressure within the substantially sealed oral cavity effective to prevent the patient's soft tissues of the upper airway from collapsing and delivering gases through the patient's nasal passageway would have been obvious to one having

ordinary skill in the art at the time of the invention given the device of Kulick in view of Cannon and Blachy.

With respect to claim 18, Kulick in view of Cannon and Blachy teaches that mouthpiece (1, Kulick) can be used to form the substantially sealed oral cavity.

The method step of forming the substantially sealed oral cavity would have been obvious to one having ordinary skill in the art at the time of the invention given the device of Kulick in view of Cannon and Blachy.

With respect to claim 19, Kulick in view of Cannon and Blachy teaches that the mouthpiece (1, Kulick) is adapted to allow normal swallowing.

With respect to claim 20, Kulick in view of Cannon and Blachy teaches that the mouthpiece does not impinge upon the tongue (column 2, lines 46-50, Kulick).

With respect to claim 21, Kulick in view of Cannon and Blachy teaches that the mouthpiece 1 includes upper and lower portions that conform to an anatomy of the patient's upper and lower dental structures. Kulick discloses bite blocks 2 located near the first molar teeth to limit the closure of the teeth (See Brief Description of the Drawing Figures, Figure 7's Description). Kulick's bite blocks 2 contain upper and lower portions that serve to conform to an anatomy of the patient's upper and lower dental structures.

With respect to claim 22, it is inherent that if the device of Kulick in view of Cannon and Blachy are capable of conforming to the anatomy of a patient's upper and lower dental structure, then it is also capable of maintaining the upper and lower dental structures of a patient at a fixed distance relative to another. Further, the mouthpiece

would allow for this because it does not move in the patient's mouth, thus the upper and lower dental structures remain at a fixed distance.

With respect to claim 23, Kulick in view of Cannon and Blachy teaches that the mouthpiece 1 is adapted to expand the size of the substantially sealed oral cavity in the mouth, since it was shown in the rejection of claims 21 and 22 that it is adapted to maintain the upper and lower dental structures at a fixed distance from one another.

With respect to claim 24, Kulick in view of Cannon and Blachy teaches that the mouthpiece 1 includes a first end of a hollow elongate member coupled to mouthpiece 1 and thereby in communication with the substantially sealed oral cavity and a second end coupled to a negative pressure generator (8) (See Figure 2 and column 4, lines 10-11, Kulick).

With respect to claim 25, Kulick in view of Cannon and Blachy teaches that the hollow elongate member (7, Kulick) is coupled to the mouthpiece (1), which is adjacent an opening of patient's mouth.

With respect to claim 25, Kulick in view of Cannon and Blachy teaches a mouthpiece (1) with a sidewall (Figure 2 - Kulick) and also a positioning member (2).

The recitations that the mouthpiece including the sidewall is "adapted to be positioned over an opening of a human mouth" and the positioning member is "adapted to fit within the mouth to maintain the mouthpiece at a fixed position" have not been considered since it has been held that the recitation that an element is "adapted to" perform a function is not a positive limitation but only requires the ability to so perform.

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It does not constitute a limitation in any patentable sense. *In re Hutchinson*, 69 USPQ 138.

With respect to claim 26, Kulick in view of Cannon and Blachy teaches a mouthpiece (1) including a sidewall (3) adapted to be positioned over an opening of the patient's mouth, and a positioning member (bite blocks) (2) adapted to fit within the mouth to maintain the mouthpiece at a fixed position.

With respect to claim 27, Kulick in view of Cannon and Blachy teaches a negative pressure generator (8 – Kulick). The use of the negative pressure generator to operate at pressure in the range of about 0 cm to –60 cm of water has been taken to be an intended use recitation of the negative pressure generator apparatus. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitation. *Ex parte Masham*, 2 USPQ2d 1647 (1987). *In re Paulsen*, 30 F. 3d 1475, 31 USPQ 2d 1671 (Fed Cir. 1994)

With respect to claim 28, Kulick in view of Cannon and Blachy teaches a negative pressure generator (8 – Kulick). The use of the negative pressure generator to remove air from the substantially sealed cavity at a rate that is in the range of about 0cc/minute to 50cc/minute has been taken to be an intended use recitation of the negative pressure generator apparatus. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed

structural limitation. *Ex parte Masham*, 2 USPQ2d 1647 (1987). *In re Paulsen*, 30 F. 3d 1475, 31 USPQ 2d 1671(Fed Cir. 1994)

With respect to claim 29, it is obvious that any negative pressure created within a substantially sealed oral cavity is further effective to remove secretions therefrom, as secretions would be drawn towards the flow of negative pressure leaving the oral cavity.

Claims 9 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kulick (U.S. 6,464,209) in view of Cannon (U.S. 7,021,312) and Blachy et al. (U.S. 4,270,531), and further in view of Curti (US 6,665,385).

Cannon does not teach the nasal mask 14 having first and second tubular members extending therethrough and in communication with the patient's nasal passageway, with the first tubular member being adapted to deliver gases through the patient's nasal passageway and the second tubular member being adapted to allow a gas sample to be taken from the nasal passageway.

However Curti in a nasal cannula teaches first 13 and second 14 tubular members being adapted to deliver gases through the patient's nasal passageway with the first tubular member being adapted to deliver gases through the patient's nasal passageway and the second tubular member 14 being adapted to allow a gas sample to be taken from the nasal passageway. "The preferred nasal cannula used in this procedure is a cannula which insufflates the patient with oxygen through one nare of a cannula and separately samples the exhaled gases by drawing the exhaled gas from the other nare into a conventional carbon dioxide analyzer" (Background of the Invention, Column 1, Lines 15-20). It would be obvious to modify the face mask of Bibi

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to include the nasal cannula of Curti, as doing so would allow one to supply oxygen through one tubular member and allow a gas sample to be taken from the other tubular member.

It would have been obvious to one of ordinary skill in the art to use the teachings of Cannon in combination with Curti to modify the face mask of Kulick to include first and second tubular members so that a patient could be provided with oxygen through one nasal passageway and so that a gas sample of carbon dioxide could be obtained from the patient's other nasal passageway.

With respect to claim 9, Kulick discloses the invention with the exception of the nasal mask including first and second tubular members extending therethrough and in communication with the patient's nasal passageway, with the first tubular member being adapted to deliver gases through the patient's nasal passageway and the second tubular member being adapted to allow a gas sample to be taken from the nasal passageway.

Cannon teaches a nasal mask 14. However Cannon does not teach the nasal mask 14 having first and second tubular members extending therethrough and in communication with the patient's nasal passageway, with the first tubular member being adapted to deliver gases through the patient's nasal passageway and the second tubular member being adapted to allow a gas sample to be taken from the nasal passageway.

Curti teaches a nasal cannula having first 13 and second 14 tubular members being adapted to deliver gases through the patient's nasal passageway with the first

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tubular member being adapted to deliver gases through the patient's nasal passageway and the second tubular member 14 being adapted to allow a gas sample to be taken from the nasal passageway. "The preferred nasal cannula used in this procedure is a cannula which insufflates the patient with oxygen through one nare of a cannula and separately samples the exhaled gases by drawing the exhaled gas from the other nare into a conventional carbon dioxide analyzer" (Background of the Invention, Column 1, Lines 15-20). It would be obvious to modify the face mask of Bibi to include the nasal cannula of Curti, as doing so would allow one to supply oxygen through one tubular member and allow a gas sample to be taken from the other tubular member. It would have been obvious to one of ordinary skill in the art to modify the face mask of Kulick/Cannon/Blachy to include first and second tubular members, as taught by Curti, so that a patient could be provided with oxygen through one nasal passageway and so that a gas sample of carbon dioxide could be obtained from the patient's other nasal passageway.

With respect to claim 16, neither Kulick, Cannon, or Blachy expressly teach a second tubular member in communication with the patient's nasal passageway for allowing a gas sample to be taken from the nasal passageway.

However, Curti teaches a nasal cannula having first 13 and second 14 tubular members being adapted to deliver gases through the patient's nasal passageway with the first tubular member being adapted to deliver gases through the patient's nasal passageway and the second tubular member 14 being adapted to allow a gas sample to be taken from the nasal passageway (column 1, lines 15-20). It would be obvious to

modify the mask of Kulick/Cannon/Blachy to have the nasal cannula as taught by Curti, as doing so would allow one to supply oxygen through one tubular member and allow a gas sample to be taken from the other tubular member.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brandon Jackson whose telephone number is (571)272-3414. The examiner can normally be reached on Monday - Friday 8-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on (571)272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Brandon Jackson
Examiner
Art Unit 3772

BLJ


PATRICIA BIANCO
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TECHNOLOGY CENTER 3700

3/31/07